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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Matthew L. Tripp

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1628

NOTIFICATION DATE

DELIVERY MODE

10/01/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,388	<b>Applicant(s)</b> TRIPP ET AL.	
	<b>Examiner</b> SHIRLEY V. GEMBEH	<b>Art Unit</b> 1628	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 236,238 and 240-256 is/are pending in the application.
- 4a) Of the above claim(s) 250-256 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 236,238 and 240-249 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I (claims 236, 238 and 240-249) in the reply filed on 8/26/10 is acknowledged.

Applicant further elects the species tetrahydro-isohumulone in claim 236, ursolic acid in claim 240 and oleanolic acid in claim 241.

Claims 250-256 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/26/10.

Applicant argues that "this election is traversed as to Claims 250-256 subject to rejoinder. Applicants maintain that a finding of patentability as to Group I, composition claims 236, 238, and 240-249 per se renders the methods of using said compositions patentable"

In response the traversal it is not a proper traversal because they failed to point out the deficiencies of the restriction requirement. The claims were found to lack unity and in the absence of any evidence/argument to the contrary, the restriction requirement is maintained and made final.

### **Status of Claims**

2. Claims 236, 238 and 240-256 are pending. Claims 236, 238 and 240-249 are elected and claims 250-256 are withdrawn based on the restriction requirement discussed in para. 1 above.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 236, 238 and 240-248 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US Patent 6,391,346) and Babish et al. (US 2002/0068098) and as evidenced by Hill et al. (GB 2,336,363).

Newmark et al. teach an orally administered composition for reducing inflammation comprising a hops extract (as required by instant claims 236 and 238, therefore the composition of Newmark would be expected to comprise tetrahydro-isohumulone, see abstract and col. 4, lines 65-67 and as evidenced by Hill et al. (GB 2,336,363, see page 4, lines 1-3), a basil extract (i.e., ursolic acid, see col. 6, lines 43-45, as required by instant claims 236 and 240). It should be noted that ursolic acid extracted from basil or from rosemary will have the same compound structure and activity therefore no patentable weight is given to the product obtained from another extract because the courts have held that if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

This rejection is also consistent with that held by the courts in *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976), which held that: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the

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issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

Likewise, the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685 (1972)).

Newmark further teaches that the hops extract is from 5.5%-8-5% (as required by instant claim 245, see col. 4, lines 65-67 and would reasonably expect that the composition would also comprise at least 0.5 mg of tetrahydro-isohumulone, as required by instant claim 242) and the ursolic acid is from 1-3% (see col. 6, lines 44-45, as required by instant claim 246 and would reasonably comprise at least 0.5% ursolic acid as required by instant claim 243) in a pharmaceutically acceptable carrier (see col. 7, lines 1-3, as required by instant claim 248).

However Newmark is silent of the specific contents extracted from hops and further fails to teach that the composition comprises oleanolic acid. Nonetheless in the background section of the Newmark teaches that ursolic and oleanolic acid are well known in the art for possessing anti-inflammatory properties (see col's. 1 and 2).

Babish et al. teaches a formulation /composition for inhibiting inflammatory response in animals comprising a first component and a second component wherein the second component are from botanical extracts of ursolic acid and oleanolic acid (see

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page 4, para 0036 as required by instant claim 1). Babish further teaches that the composition may comprises up to 20 mg triterpenes (see para 0040, note that oleanolic acid is a triterpene, therefore would reasonably comprise 0.001-10% by weight, as required by instant claim 246)

However Babish fails to teach that the first component (i.e., tetrahydro-isohumulone) as required by instant claim 236.

It would have been obvious to one of ordinary skill in the art to have been motivated to expand Newmarks composition to include Babish's composition for treating or inhibiting inflammatory response in a mammal because Newmark teaches in the background section that ursolic acid and oleanolic acid have been found to possess significant anti-inflammatory properties. Therefore one of ordinary skill in the art would have been motivated to incorporate Babish's composition into Newmark's composition with a reasonable expectation of success in doing so (see Newmark col. 1 and 2).

With regards to the exact concentrations and ratios not taught specifically with regards to claim 247, these are parameters that are within the purview of one of ordinary skill in the art. Based on the composition and type of formulation it is well within the purview of one of ordinary skill in the art to optimize. For example in Example 4 of Babish the formulation comprises 6.0 mg/kg oleanolic acid and ursolic acid per day and 0.01 mg/kg per day of the first component. Since tetrahydro-isohumulone is known in the art to have analgesic activity and component 1 of Babish is also known for its analgesic activity, one of ordinary skill in the art would have reasonably substituted

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Babish's compound 1 for Newmarks hops extract tetrahydro-isohumulone and had a ratio of 100:1 of the second component based on Example 4 of Babish.

Therefore the claimed invention of instant claims 236, 238 and 240-248 would have been obvious at the time of filing.

4. Claims 236, 238 and 240-249 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US Patent 6,391,346) and Babish et al. (US 2002/0068098) and as evidenced by Hill et al. (GB 2,336,363).

Newmark and Babish are applied here in their entirety as it relates to claims 236, 238 and 240-248. However Newmark fails to teach that their composition comprises glucosamine. Babish teaches that the composition further comprises glucosamine (see page 13, claim 5).

One of ordinary skill in the art would have been motivated to expand the composition of Newmark to include Babish's composition of glucosamine because Babish teaches that it may increase the rate of glucosamine or chondrotin sulfate to normalize joint movement and reduce symptoms of osteoarthritis (0019).

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140



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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 236, 238 and 240-249 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1, 6-10, 13-15** of U.S. Patent Application No. **10557293**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

- • Both sets of claims refer to a composition comprising tetrahydro-isohumulone. Since the claim language of the instant claims is open (i.e., the term comprising) it does not exclude other active agents of being present in the composition), therefore the current application (claims 236, 238 and 240-249) and the co-pending '293 claims (claims **1, 6-10, 13-15**) are obvious variation of each other.
- • In view of the foregoing, the copending application claims and the current application claims are obvious variations.

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6. Claims 236, 238 and 240-249 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-8**, of U.S. Patent Application No. **11/729696**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

- • Both sets of claims refer to a composition comprising a specie of hops (i.e., tetrahydro-isohumulone in the instant claim and dihydro-isohumulone in the copending '696 claims in combination with oleanolic acid and an extract of rosemary which reasonably encompass ursolic acid as required by instant claims therefore the current application (claims 236, 238 and 240-249) and the co-pending '696 claims (claims **1-8**) are obvious variation of each other.
- • In view of the foregoing, the copending application claims and the current application claims are obvious variations.

7. Claims 236, 238 and 240-249 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1, 9, 13-14, 18-27 and 152-154**, of U.S. Patent Application No. **10/464410**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

- • Both sets of claims refer to a composition comprising a specie of hops (i.e., tetrahydro-isohumulone in the instant claim and dihydro-isohumulone in the

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compending '696 claims in combination with oleanolic acid and an extract of rosemary which reasonably encompass ursolic acid as required by instant claims therefore the current application (claims 236, 238 and 240-249) and the co-pending '696 claims (claims **1-8**) are obvious variation of each other as an inflammatory therapeutic composition.

- • In view of the foregoing, the compending application claims and the current application claims are obvious variations.

8. In summary, it is noted that applicant has numerous issued patent and pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s) for each and every one considered to be the same or similar subject matter.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brandon Fetterolf** can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./  
Examiner, Art Unit 1628  
9/17/10

/Christine J Saoud/  
Primary Examiner, Art Unit 1647